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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,689	11/10/2003	Allan R. Dunn	1.275.03	4644

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	**PAPER NUMBER**
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,689	DUNN, ALLAN R.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-7,9-11 and 13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,12 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

1a. Applicant's election with traverse of the invention of Group II (claims 2, 4, 12, 20), filed in the reply filed on 08 January 2007 is acknowledged.

Applicant contends that the process of claims 1-3, contains all the limitations of the elected product claims 4, 8, 12 and 20. Accordingly, Applicant requests to rejoin corresponding process claims 1-3 to the elected claims.

As was set forth in the restriction requirement mailed on 04 October 2006, Inventions I and II are related as a process and product used. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the composition of Groups II, as claimed can be used in a method of treating idiopathic short stature.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Claims:

1b. Claims 1-20 are pending, of which claims 4, 8, 12 and 20 are drawn to the elected invention, and will be searched and examined. Claims 1-3, 5-7, 9-19 are withdrawn from consideration by the Examiner as they are drawn to non-elected invention.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12 October 2004 has been received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Duplicate Claims:

3. Applicant is advised that should claim 4 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Likewise,

should claims 8 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

It appears that there is no difference between the compositions of claim 4 and of claim 12, they both encompass 0.025 mg to 0.249 mg of growth hormone in 1 to 10 ml buffer, while the compositions of claims 8 and 20 both encompass 0.5 mg to 10.0 mg growth hormone per milliliter of buffer solution.

Claim Rejections - 35 USC § 112, second paragraph:

4. Claims 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 12 are drawn to a composition comprising 0.025 mg to 0.249 mg of purified growth hormone per kg of body weight dissolved in a buffer solution of between 1 to 10 milliliters. However, it is unclear whether 0.025 mg of growth hormone has to be dissolved in 1 or 10 ml of buffer, and likewise, whether the 0.249 mg has to be dissolved in 1 or 10 ml of buffer. Clarification is required.

Claim Rejections under 35 U.S.C. §103:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 4, 8, 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn, (U.S. Patent Number 5,368,051, 11/29/1994).

Claims 4 and 12 are drawn to a composition comprising 0.025 mg to 0.249 mg of purified growth hormone per kg of body weight dissolved in a buffer solution of between 1 to 10 milliliters. Claims 8 and 20 are drawn to a composition comprising 0.5 mg to 10.0 mg of purified growth hormone per milliliter of buffer.

Dunn does not teach the specific concentrations of growth hormone in buffer solution recited in the instant claims.

Dunn teaches purified growth hormone dissolved in a buffer solution, preferably in Hank's solution at dosages 1 mg to 1.5 mg of growth hormone per milliliter of buffer and an individual dosage of 0.25 mg to 0.75 mg per kg of body weight, (see column 5, lines 33-68).

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to dissolve in the buffer as taught by Dunn, by just increasing the concentration of the growth hormone. The person of ordinary skill in the art would be able to increase the concentration of the well known growth hormone in the

buffer and would be able to achieve the claimed dosages, without any inventive contribution on their part. It would have been within the ordinary skill of the art to modify and optimize the dosage and concentration of growth hormone in the buffer for various reasons, for example, for research purposes or for clinical purposes, with reasonable expectation of success. Accordingly, the invention, taken as a whole, is prima facie obvious over the cited prior art.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
16 February 2007

Brenda Brumback

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SUPERVISORY PATENT EXAMINER
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